Patients Injected with Plutonium (Draft Report of 5-24-74)

1. Status of informed consent (recommendations 1 and 3 of enclosure 1).

   a. Drs. W. Weyzen, BER, and A. Brues, Argonne National Laboratory, visited the attending physician of the recently studied patient who lives in Italy, Texas. The 82 year old physician, who will retire soon, willingly offered to comply with the wishes of the Commission in providing disclosure to the patient and in obtaining informed consent to continued participation in the study. The physician anticipates no difficulty in obtaining the patient's cooperation.

   b. Drs. W. Burr and S. Marks, BER, met with officials of the University of Rochester and attending physicians of three Rochester patients, two of whom participated in the 1973 study. The physician of the two patients who were studied recently willingly offered to provide disclosure to and obtain informed consent from the patients during their next monthly office visits.

      The physician of the third patient regarded disclosure in that case as medically indefensible on the grounds that disclosure carries a high risk of potential harm to that patient. His supporting information is as follows:

      (1) the patient is senile and incapable of receiving proper disclosure or providing informed consent;

      (2) the husband of the patient is seriously ill after open heart surgery;

      (3) the children are estranged from the parents and may use such information to the detriment of the patient.

The physician will submit the question of nondisclosure in this case to the University Committee on Human Experimentation and will abide by the decision of that committee. A report based on the deliberations and findings of the committee will be submitted to AEC by University officials.

2. Offer of medical surveillance (recommendation 2).

The offer to provide payment for medical surveillance of patients was made in discussions with attending physicians.

3. Disclosure to next of kin of exhumed patient (recommendation 4).

Implementation of this recommendation was deferred until policy is established relative to continuation of the exhumation program in order to coordinate disclosure here to that to be decided for the next of kin included under recommendations 6 and 7 (see 5. and 6. below).

4. Report of ad hoc scientific committee (recommendation 5).

The ad hoc scientific committee appointed by the Director, BER, to advise the Commission regarding the scientific merit of the exhumation program unanimously and strongly recommended continuation of the program on the grounds of scientific merit. The committee did not undertake to evaluate ethical, medical or public opinion aspects. The following statements are quoted from the committee's draft report (enclosure 1), which is subject to later revision:

"This report is intended only to be an evaluation of the scientific merit of a proposed program to exhume the bodies of those few persons who received intravenous injections of plutonium during the period 1945-1947. We are aware of the fact that there are a number of related aspects which are of an ethical, medical or public opinion nature.

This report is not intended to give our evaluation of these aspects. . . . . .The unanimous opinion of this group is that the proposed program of exhumation proceed in an orderly manner. . . . . .Thus it is mandatory that an effort be made to obtain a material balance by analyzing the content and distribution of plutonium remaining in the bodies of those persons that were injected with a (small) known amount of plutonium. . . . . .Results obtained in the exhumation program will give a much more complete accounting of plutonium metabolism in man and its distribution in tissues other than bone. . . . . .Material obtained by exhumation will provide the unique opportunity of identifying and quantifying the microscopic distribution of plutonium with respect to the age at the time of injection and the duration of exposure. . . . . .Such information will be exceedingly useful in determining the local effects of plutonium dose rates. . . . . .The fact that there are only a small number of persons in the injected group is not considered to be a problem by the committee. . . . . .There are some limitations and problems associated with the proposed exhumation project. . . . . .The population consisted of persons of mixed ages at exposure and all had serious medical-health problems at the time of injection, thus somewhat limiting the interpretation of data as representing the 'normal' population sample. . . . . .The integrity, completeness, and condition of the bodies to be exhumed may not be adequate for a satisfactory recapitulation of the plutonium present at death. In particular the ravages of chemical reactions in the grave may lead to some incorrect interpretations. . . . . .There appears to be little to be gained

by recovery of cremated bodies. . . . . .These known limitations on the quantity and quality of material to be obtained by exhumation appear, however, to be nearly negligible with respect to the value of the potential results. The program would be of merit if it only provided a basis for a more accurate method of estimating occupational exposures. The program, however, can realistically be expected to yield much more valuable scientific data."

In view of the committee's action, continuation of the exhumation program in a manner approved by the Argonne Review Committee for Research on Human Subjects is recommended.

5. Disclosure to previously contacted next of kin of deceased not exhumed (recommendation 6).

   a. If continuation of exhumation program is approved, provide disclosure to next of kin who previously approved exhumation. Do not contact again persons who refused to consent to exhumation.*

   b. If continuation of exhumation program is not approved, do not contact again persons previously approached irrespective of their earlier attitude.*

6. Disclosure to those next of kin of deceased who were not previously contacted (recommendation 7).

   a. If continuation of exhumation program is approved, obtain proper informed consent to exhumation.

   b. If continuation of exhumation program is not approved, do not contact next of kin.*

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*OGC is studying legal aspects.

7. Recommendations 8 and 9 required no further action.

8. Dr. Liverman and Mr. Greenleigh discussed the projected course of action with representatives of DOD on May 22, 1974 (recommendation 10).

9. As a new recommendation, the Director, BER, shall discuss with Presidents of the Universities of California and Chicago the possibility of public interest in this matter.

DRAFT II
Marks/bel
5/10/74

ENCLOSURE 1

PATIENTS INJECTED WITH PLUTONIUM

The attached table provides a summary of current information regarding disclosure to individual patients based on the recently completed inquiry.

The following recommendations with respect to future actions were formulated at a meeting of representatives of BER, OGC and INS:

1. Attending physicians of living patients shall be advised of the ethical need to provide disclosure to such patients. The approach to the patients would be expected to take into account available information regarding the possibility or, in one case, certainty of disclosure in 1945-1947. The Director, BER, will determine the procedure for contacting the attending physicians who are to inform the patients or their families.
2. The patients shall be offered a program of regular medical surveillance at government expense.
3. Studies shall be continued on the living patients with scrupulous regard for compliance with DHEW guidelines as recommended now by the Argonne Laboratory Review Committee for Research Projects Involving Human Subjects. Proper informed consent is a necessary element of such compliance.
4. Disclosure shall be provided to the next of kin of the exhumed patient.
5. A scientific committee chosen by the Director, BER, shall review the program of exhumation of the deceased and shall advise AEC as to whether the scientific merit of the exhumation program warrants its resumption at an appropriate later date.
6. Next of kin approached already for permission for exhumation shall be contacted again to correct any misleading information that they may have

received during previous discussion. Such interviews shall be deferred until decision of committee in 5. is available. If AEC decides to continue exhumation program, reaffirmation of consent may be required.

7. All reasonable efforts shall be made to contact next of kin of all deceased unless the Director, BER, determines on the basis of the next of kin's health that disclosure should not be made.
8. Unless indicated by problems that might arise in the implementation of the above program or by future events, outside review will not be requested.
9. With a public response statement already available, decision regarding public release will be deferred. Such release may be considered desirable in relation to July meeting of International Congress for Radiation Research.
10. Projected program as approved by Commission shall be discussed with DOD.

ENCLOSURE 2

Draft Report of Ad Hoc Committee convened on May 22, 1974, to provide recommendations on the scientific merit of studying the fate of plutonium in deceased persons who had received injections of plutonium years earlier.

The committee consisted of Drs. E. P. Cronkite, Chairman, Medical Department, Brookhaven National Laboratory; M. Goldman, Director, Radiobiology Laboratory, University of California, Davis; B. J. Stover, Professor of Pharmacology, University of North Carolina; and R. V. Talmage, Director of Orthopaedic Research, University of North Carolina.

This report is intended only to be an evaluation of the scientific merit of a proposed program to exhume the bodies of those few persons who received intravenous injections of plutonium during the period 1945-1947. We are aware of the fact that there are a number of related aspects which are of an ethical, medical or public opinion nature. This report is not intended to give our evaluation of these aspects.

The unanimous opinion of this group is that the proposed program of exhumation proceed in an orderly manner. This decision is based on the following considerations:

1. The "Langham equation" that attempts to relate urinary (and fecal) excretion rates to the amount of plutonium present in the exposed person was derived from data obtained from this small group of persons that were given plutonium intravenously. This equation, which was developed from early data and from data obtained five years after injection, is interpolated and extrapolated almost universally by health physicists and radiation protection specialists in estimating body burdens of occupationally exposed persons. Thus, it is mandatory that an effort be made to obtain a material balance by analyzing the content and distribution of plutonium remaining in the bodies of those persons that were injected with a (small) known amount of plutonium. The results will provide a means of evaluating the validity of estimating burdens by the Langham equation or a modification thereof.

2. The distribution of plutonium in soft tissues and bone marrow is also of importance. Results obtained in the exhumation program will give a much more complete accounting of plutonium metabolism in man and its distribution in tissues other than bone.

3. Material obtained by exhumation will provide the unique opportunity of identifying and quantifying the microscopic distribution of plutonium with respect to the age at the time of injection and the duration of exposure. For example, data can be obtained which will aid in determining the role of surface deposits of a known dose of plutonium as they may have affected the subsequent activities of adjacent bone forming systems. Such information will be exceedingly useful in determining the local effects of plutonium dose rates.

4. The fact that there are only a small number of persons in the injected group is not considered to be a problem by the committee. The plutonium exhumations, however limited, have as one of its main goals the determination of certain relationships useful in interpreting extensive animal experimentation on plutonium metabolism and toxicity as it may relate to man.

There are some limitations and problems associated with the proposed exhumation project.

1. The total number of injected persons is small and even if all of the tissue were to be analyzed the ability to perform extensive statistical analyses would be minimal.

2. The population consisted of persons of mixed ages at exposure and all had serious medical-health problems at the time of injection, thus somewhat limiting the interpretation of data as representing the "normal" population sample.

3. The integrity, completeness and condition of the bodies to be exhumed may not be adequate for a satisfactory recapitulation of the plutonium present at death. In particular the ravages of chemical reactions in the grave may lead to some incorrect interpretations.

4. There appears to be little to be gained by recovery of cremated bodies.

These known limitations on the quantity and quality of material to be obtained by exhumation appear, however, to be nearly negligible with respect to the value of the potential results. The program would be of merit if it only provided a basis for a more accurate method of estimating occupational exposures. The program, however, can realistically be expected to yield much more valuable scientific data.